

DENMAT HYDROGEN PEROXIDE ORAL RINSE- hydrogen peroxide oral rinse

Den-Mat Holdings, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Hydrogen peroxide 1.5% (w/v).....

Bacteria reducing rinse and oral debriding agent/oral wound cleanser

For temporary use to reduce bacteria in the mouth to cleanse or facilitate healing of minor mouth irritations, such as canker sores, minor wounds or minor gum inflammation resulting from dental procedures, dentures, orthodontic appliances, accidental injury or other irritations of the mouth and gums.

Do not use this product for more than 7 days unless directed by a dentist or physician.

When using this product, do not swallow.

Stop use and ask a doctor if

- sore mouth symptoms do not improve within 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older: fill dose cup to 10 mL (two teaspoons) and rinse around in the mouth over affected area for at least 1 minute, then spit out

Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician

Children under 12 years of age should be supervised in the use of the product

Children under 6 years of age: consult a dentist or physician

Other information store at controlled room temperature 68 – 77°F (20 – 25°C)

Inactive Ingredients Water, glycerin, sodium citrate, cremophor RH 40, flavor, tego betain ZF, citric acid, sodium benzoate, sodium fluoride, xylitol.

Questions? 800-433-6628

DO NOT USE IF PLASTIC SEAL IS DAMAGED, OPEN OR MISSING

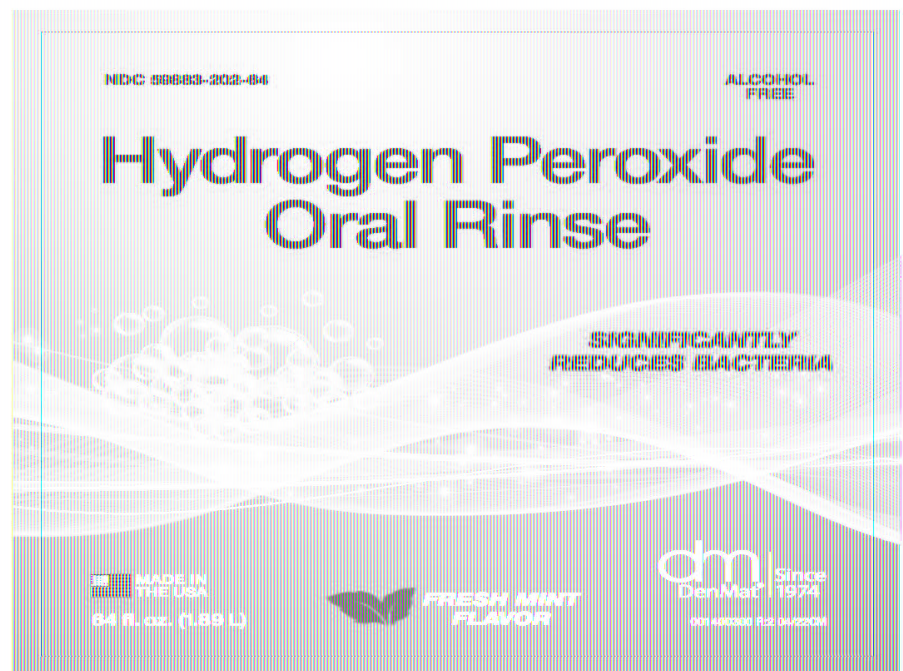
Drug Facts	
Active ingredient[s]	Purposes
Hydrogen peroxide 1.5% (w/v).....	Bacteria reducing rinse and oral debriding agent/oral wound cleanser
Use[s] ■ For temporary use to reduce bacteria in the mouth before and after dental procedures. Other uses include removal of oral debris and cleansing or healing of minor mouth irritations, such as canker sores, minor wounds and minor gum inflammation resulting from dental procedures, dentures, orthodontic appliances, accidental injury or other irritations of the mouth and gums.	
Warnings Do not use this product for more than 7 days unless directed by a dentist or physician.	
When using this product , do not swallow.	
Stop use and ask a doctor if ■ sore mouth symptoms do not improve within 7 days ■ irritation, pain or redness persists or worsens ■ swelling, rash or fever develops	
Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Adults and children 6 years of age and older: fill dose cup to 10 mL (two teaspoons) and rinse around in the mouth over affected area for at least 1 minute, then spit out ■ Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician ■ Children under 12 years of age should be supervised in the use of the product ■ Children under 6 years of age: consult a dentist or physician	
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Manufactured by
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Lompoc, CA 93436
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001400301 R:3 04/22CM



LOT
EXP



hydrogen peroxide oral rinse rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59883-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
MINT (UNII: FV98Z8GITP)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-202-64	1893 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/02/2022	
2	NDC:59883-202-28	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/02/2022	
3	NDC:59883-202-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/02/2022	

Labeler - Den-Mat Holdings, LLC (809857704)

Registrant - Den-Mat Holdings, LLC (809857704)

Establishment

Name	Address	ID/FEI	Business Operations
Den-Mat Holdings, LLC		809857704	manufacture(59883-202) , label(59883-202) , pack(59883-202)

Revised: 5/2022

Den-Mat Holdings, LLC